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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,549

12/05/2003

Mary J. Laughlin

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ROPES & GRAY LLP  
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BOSTON, MA 02110-2624

EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,549	<b>Applicant(s)</b> LAUGHLIN ET AL.	
	<b>Examiner</b> Lora E. Barnhart	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,5,9-12,21-43,48,50-54,56,57 and 62-69 is/are pending in the application.
- 4a) Of the above claim(s) 5,8,22,37-39 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,10-12,21,23-36,40-43,50-54,56,57 and 62-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/26/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/09 has been entered.

### ***Response to Amendments***

Applicant's amendments filed 2/26/09 to claims 1, 5, 48, 54, and 57 have been entered. No claims have been canceled or added in this reply. Claims 1, 2, 4, 5, 9-12, 21-43, 48, 50-54, 56, 57, and 62-69 remain pending in the current application, of which claims 1, 2, 4, 10-12, 21, 23-36, 40-43, 50-54, 56, 57, and 62-69 are being considered on their merits. Claims 5, 9, 22, 37-39, and 48 remain withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 2, 4, 10-12, 21, 23-36, 40-43, 50-54, 56, 57, and 62-69 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendments to independent claims 1, 5, 48, 54, and 57 introduce the negative limitation that various cells be enriched from bone marrow mononuclear cells (BMMCs) "without leucopheresis or culturing the cells." There is no basis for this exclusion, either implicit or explicit, in the as-filed specification. The term "culturing" is not provided with a limiting definition in the specification, so it must be given its broadest reasonable interpretation. See M.P.E.P. § 2111.01. DICTIONARY DEFINITION OF CULTURING. Therefore, any step in which cells are placed into any media for any purpose for any length of time is encompassed in the term "culturing."

The specification repeatedly indicates that the progenitor and stem cells are cultured prior to administration for varying times and in varying media. See, for example, page 19, lines 4-21; page 20, line 7, through page 21, line 9; and the working examples at page 27, line 11, through page 28, line 6. In order for cells not to be considered "cultured," a method would necessarily isolate cells in the absence of media and administer them immediately to a recipient without including any carrier. There is no basis for this embodiment in the as-filed specification, which clearly teaches otherwise.

The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. § 112, first paragraph. See, e.g., *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original). See M.P.E.P. § 2163.05. Similarly, in this case, although it is easy to envisage a method that omits a culturing step, there is simply no disclosure of such a method in the as-filed specification.

Applicant alleges that M.P.E.P. § 2175.05(i) allows this amendment (Reply, page 10, last paragraph). These arguments have been fully considered, but they are not persuasive. The section of the M.P.E.P. to which applicant refers clearly reads, "If alternative elements are **positively** recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) [emphasis added]." In this case, there appears to be no **positive** recitation of an embodiment of the method that lacks any culturing. In *Johnson*, the patent at issue listed fifty specific choices pertaining to the contested limitation, and applicant was attempting to eliminate a few of those specific choices (at 195). In this

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case, applicant attempts to claim an embodiment that is not positively recited as an option for the claimed invention. Therefore, the cited section does not apply in this case and cannot serve to preclude a new matter rejection.

***Claim Rejections - 35 USC § 103***

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection over the claims. However, removal of new matter may result in the reinstatement of the art rejection of record.

***No claims are allowed.***

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/  
Primary Examiner, Art Unit 1651